



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 800, 801, 808, and 874

[Docket No. FDA-2020-D-1380]

Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products;
Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products.” This guidance document is intended to describe hearing aids, personal sound amplification products (PSAPs), their respective intended uses, and the regulatory requirements that apply to these products. The FDA Reauthorization Act of 2017 (FDARA) directed FDA to update and finalize the draft guidance entitled “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products,” issued on November 7, 2013. This final guidance fulfills this FDARA requirement and supersedes “Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products,” dated February 25, 2009.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2020-D-1380 for "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:
<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification

Products” to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Shu-Chen Peng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1224, Silver Spring, MD 20993-0002, 301-796-6481.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115-52) directs FDA to establish a category of over-the-counter (OTC) hearing aids through rulemaking, and mandates that FDA establish various requirements for this category of devices. Published elsewhere in this edition of the *Federal Register*, FDA is issuing a final rule (“rule”) to establish the OTC category of hearing aids and to implement the requirements of FDARA. In the rule, FDA has also outlined multiple related changes to the overall regulatory framework for hearing aids to harmonize existing regulations with the new OTC category while continuing to provide a reasonable assurance of safety and effectiveness.

FDARA also directed FDA to update and finalize the draft guidance entitled “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products,” issued on November 7, 2013. To fulfill this requirement of FDARA, FDA is issuing this final guidance, which supersedes the February 25, 2009, final guidance. This final guidance reflects the new regulatory framework for hearing aids in the rule.

This guidance document identifies current applicable legal requirements under the Federal Food, Drug, and Cosmetic Act for hearing aids and for PSAPs. This guidance is intended to describe hearing aids, PSAPs, their respective intended uses, and the regulatory requirements that apply to both types of products. For information on certain situations in which

FDA does not intend to enforce certain regulatory requirements, you may refer to the preamble to the rule that is published elsewhere in this edition of the *Federal Register*.

A notice of availability of the draft guidance appeared in the *Federal Register* of October 20, 2021 (86 FR 58192). FDA considered comments received and revised the guidance as appropriate in response to the comments, including aligning the guidance with the rule.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov> and <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. Persons unable to download an electronic copy of "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1832 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is

not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR Part	Topic	OMB Control No.
807, subpart E	Premarket notification	0910-0120
814	Premarket approval	0910-0231
800, 801, and 809	Medical Device Labeling Regulations	0910-0485
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting	0910-0437
1000 through 1050	Electronic Products	0910-0025

Dated: August 5, 2022.
Lauren K. Roth,

Associate Commissioner for Policy.

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